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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/702,134
Filing Date: October 31, 2000
Appellant(s): BOUKHAROV ET AL.

Thomas E. Holsten
David R. Marsh
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 22, 2005.

A statement identifying the real party in interest is contained in the brief.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

In particular, Appellants brief identifies the related decision by the Board in *In re Fisher* (U.S. Application No. 09/619,643, B.P.A. I. Appeal No. 2002-2046, Fed. Cir. Case No. 04-1465).

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1, 8-12 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Genbank Accession Number U50333, February 1997.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claim Rejections - 35 USC § 101

Claims 1, 8-12 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claimed subject matter is not supported by a specific, substantial, and credible asserted utility because the disclosed uses are generally applicable to broad classes of this subject matter. Further characterization of the claimed subject matter would be required to identify or reasonably confirm a Areal world≅ use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The specification teaches that SEQ ID NO 7212 is one of a group of over 50,000 large genomic fragments obtained from rice (see entire specification). The specification asserts that a variety of uses are applicable to all of the disclosed sequences, including

use of the various sequences in genomic mapping, gene identification and analysis, plant breeding, preparation of expression constructs, preparation of transgenic plants, screening for traits, and determination of polymorphisms and of associations between polymorphisms and traits (see entire specification, particularly, e.g., pages 1, 12, and 18). However, the uses asserted in the specification are general utilities and methods of further research that are applicable to virtually any genomic nucleic acid from any plant. For example, any plant nucleic acid could be employed in genomic mapping, and any plant nucleic acid could be analyzed from the presence of genes (which genes could further be subjected to analysis); such general methods do not constitute substantial uses that are specific to one or more of the molecules disclosed by applicant. Further, while such mapping and nucleic acid analysis might eventually result in the identification of, e.g., particular regulatory elements useful in recombinant expression methods or in preparation of transgenic plants, specific polymorphisms associated with specific traits, particular open reading frames encoding useful proteins, etc., such further research and experimentation on nucleic acids also constitutes a general utility, rather than a specific and substantial "real world" use. See *Brenner v. Manson*, 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". A patent is therefore not a license to experiment with the objective of eventually identifying a specific and substantial use for a product or method. With regard to SEQ ID NO: 7212 in particular, while the specification discloses that the sequence has been examined for homologies with known genes (see, e.g., Table 1),

the specification does not provide any evidence that applicants have, e.g., identified within SEQ ID NO: 7212 any particular polymorphisms associated with a trait or traits, identified any particular promoters or regulatory elements useful in methods of recombinant gene expression, determined that any of the putative open reading frames in the sequence actually encodes a protein having a specific use, etc. Accordingly, the claimed invention is not supported by a specific, substantial and credible asserted utility.

With regard to the possibility that there may exist a well-established utility for the claimed invention, it is noted that SEQ ID NO: 7212 is free of the prior art. A search of the prior art indicates that SEQ ID NO: 7212 does contain a region of significant homology with a known molecule, specifically, with a rice cDNA encoding gibberellin 20-oxidase (GENBANK Accession No. U50333, February 1997). However, an alignment of this cDNA with SEQ ID NO: 7212 reveals (in addition to multiple mismatches) multiple frameshifts within the coding sequence of the cDNA; accordingly, the prior art indicates that SEQ ID NO: 7212 and the prior art cDNA do not in fact encode the same protein. Thus, the prior art does not provide any evidence of a well-established utility for SEQ ID NO: 7212.

With regard to the rejection of claims 1 for lack of utility in the Office action of August 12, 2003, the response traversed the rejection on the following grounds. Applicant argues that the claimed invention possess numerous utilities, including those cited by the examiner in the Office action of August 12, 2003 (which utilities were identified by the examiner as being general utilities and methods of further research), as well as "obtaining protein molecules, determining the presence and/or identity of

polymorphisms, measuring the levels of an mRNA in a sample, determining the location of a corresponding DNA sequence on a physical or genetic map, probing for other molecules, obtaining other nucleic acid molecules from the same species, obtaining related protein coding sequences, obtaining promoters and other flanking genetic elements, screening cDNA genomic libraries, obtaining nucleic acid homologs, detecting and characterizing gene expression, etc." The response further argues that the uses disclosed in the specification "are directly analogous to a microscope" which is useful "to identify and characterize the structure of biological tissues in a sample, cell, or organism," and urges therefore that "the presently disclosed sequences possess the requisite utility" under 35 U.S.C. 101. Applicant states that the examiner "suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose" as the claimed molecules. Applicant urges that "there is no requirement of exclusive utility in the patent law," and states that "such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose." The response argues that the claimed molecules meet the utility requirement because they "will identify a unique subset of related sequences" which is "specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule."

Applicant's arguments have been thoroughly considered but are not persuasive. First, with regard to the list of utilities recited by Applicant at pages 19-20 of the Response, it is noted that these utilities, like the other asserted utilities noted by the examiner in the Office action of August 12, 2003, constitute general utilities and

methods of further research that are applicable to virtually any genomic nucleic acid from any plant. With regard to Applicant's argument that the claimed nucleic acids may be used "to identify and characterize other nucleic acid molecules within a sample, cell or organism" in a manner analogous to a microscope, this argument is not persuasive. Like the other general utilities discussed above, such a general use (in "identifying and characterizing" other nucleic acids) is applicable to virtually any genomic nucleic acid. While it is true that a microscope may be employed in identifying and characterizing tissues, this is also true of numerous types of equipment found routinely in laboratories, including gel electrophoresis apparatus, thermocyclers, vacuum blotters, etc.; all of these items may be used in various ways to achieve the general objective of "identifying and characterizing" biological tissues. However, a microscope is known to function in a particular way that differentiates it from these other types of equipment, and has a use in specific aspects of identification and characterization of tissues (e.g., visualization of structures) that differs from the specific uses of other types of equipment that are also useful in "identifying and characterizing" tissues. Accordingly, in contrast to the molecules of the claims, a microscope is not merely a member of a large genus of items for which specific functions have yet to be identified, but rather a well characterized piece of laboratory equipment with a specific and substantial use. Applicant has yet to identify such a specific and substantial use for SEQ ID NO: 7212. Regarding Applicant's statement that the examiner "suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose," it is noted that the examiner did not make such a statement, but rather suggested that uses

that are generally applicable to any nucleic acid cannot be considered a specific and substantial use for a particular nucleic acid molecule. It is acknowledged that a variety of different types of golf clubs may be used to hit a golf ball. However, this use in performing a specific task (i.e., hitting a golf ball) differentiates golf clubs from other types of athletic equipment (for example, tennis racquets). However, the instant specification does not disclose a substantial use that is specific either to SEQ ID NO: 7212 or, e.g., a group of molecules including SEQ ID NO: 7212 that would differentiate it from, for example, SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3, etc. Further, while it is acknowledged that SEQ ID NO: 7212 could be used to differentiate, e.g., complements of SEQ ID NO: 7212 from complements of SEQ ID NO: 1, complements of SEQ ID NO: 2, etc., such a use is not specific and substantial unless a specific and substantial use for the molecule being detected has been identified. It is again noted that research and experimentation on nucleic acids constitutes a general utility, rather than a specific and substantial "real world" use. See *Brenner v. Manson*, 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". A patent is therefore not a license to experiment with the objective of eventually identifying a specific and substantial use for a product or method. Accordingly, Applicant's arguments are not persuasive.

B. Claim Rejections - 35 USC § 112, first paragraph (Enablement)

1. Additionally, claims 1-4 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the teachings of the specification and of the prior art do not enable one skilled in the art to use molecules having any "nucleic acid sequence of SEQ ID NO: 7212 or its complement" or molecules "capable of specifically hybridizing" to such molecules, or molecules that have between 90%-100% identity with SEQ ID NO: 7212.

Claim 1 as written is sufficiently broad so as to encompass any molecule "having a nucleic acid sequence of SEQ ID NO: 7212 or its complement" (i.e., any subsequence of the recited sequences, rather than the full length molecules). Accordingly, the claims are not limited to, e.g., nucleic acids encoding a protein with a particular biological activity, but rather embrace numerous other molecules. Further, the claims as written encompass subsequences of any length of SEQ ID NO: 7212 or its complement, and further embrace flanking sequences of unspecified length and identity.

Claims 8-12 encompass molecules that are 90%-100% identical to SEQ ID NO: 7212, and which also may be flanked by sequences of any length and identity. Thus, the claims as written encompass allelic and splice variants SEQ ID NO: 7212 and fragments thereof, naturally and non-naturally occurring mutants of these sequence, variants isolated from other organisms, etc. The specification has not disclosed a specific and substantial utility even for, e.g., a particular nucleic acid consisting of SEQ ID NO: 7212, and further does not teach a biological function for the large genus of molecules encompassed by the claims, or otherwise provided guidance with respect to how such molecules may be used in a utility meeting the requirements of 35 USC 101.

Additionally, it is again noted that the prior art is silent with respect to SEQ ID NO: 7212. Accordingly, while one of skill in the art could conduct further experimentation aimed at, e.g., identifying a particular function for the molecules of the claims, such a function is not presently known, and the outcome of such experimentation cannot be predicted. Thus, it would require undue experimentation to use the claimed invention.

C. Claim Rejections - 35 USC § 112, first paragraph (Written Description)

2. Claims 1-4 and 8-12 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

It is first noted that nucleic acids consisting of SEQ ID NO: 7212 meet the written description requirements. However, none of the instant claims are limited to such a molecule. It is again noted that claim 1 as written encompasses any molecule "having a nucleic acid sequence of SEQ ID NO: 7212 or its complement" (i.e., any subsequence of the recited sequences, rather than the full length molecules). The claims are not limited to, e.g., nucleic acids sharing the same function as SEQ ID NO: 7212 or encoding a protein with a particular biological activity, but rather embrace numerous other molecules. Further, the claims as written encompass subsequences of any length of SEQ ID NO: 7212 or its complement, and further embrace flanking sequences of unspecified length and identity.

Claims 8-12 encompass molecules that are 90%-100% identical to SEQ ID NO: 7212, and which also may be flanked by sequences of any length and identity. Thus, the claims as written encompass allelic and splice variants SEQ ID NO: 7212 and fragments thereof, naturally and non-naturally occurring mutants of these sequence, variants isolated from other organisms, etc. However, the specification does not exemplify nucleic acids that have 90-99% identity with SEQ ID NO: 7212. Further, the claims recite open transitional language ("having"; "comprising"), and therefore include, e.g., molecules that are 90-100% identical with SEQ ID NO: 7212 and which further include undefined flanking sequences. As a result, the claims read on additional variants, mutants, homologues, etc., that differ completely from SEQ ID NO: 7212 with respect to both structure and function.

Additionally, while the instant claims recite structural properties for the molecules encompassed thereby, the claims fail to define the claimed molecules in terms of their functional properties. As a result, the claims as written embrace molecules with biological functions different and distinct from any function possessed by SEQ ID NO: 7212 and any protein encoded thereby. The specification does not disclose or exemplify any of the molecules embraced by the claims having an activity or function that differs from that which may be possessed by SEQ ID NO: 7212. Further, the general teachings of the art do not provide guidance with respect to how any alterations of SEQ ID NO: 7212 would affect its function, as the affects of alterations made in one nucleic acid molecule are not predictive of the affects of such changes in another, unrelated molecule. Thus, given the lack of any functional requirements in the claims,

the single molecule exemplified in the specification (SEQ ID NO: 7212) is not representative of the broad genus of molecules embraced by the claims. While the written description requirement does not require Applicant to disclose every species embraced by a claimed genus, the description of a genus is achieved by the recitation of a representative number of molecules encompassed by the genus, which molecules are usually defined by sequence. *Regents of the University of California v. Eli Lilly,* 43 USPQ2d 1398-1412. In the instant case, the particular molecule disclosed by Applicants is not representative of the broad genus claimed, and the written description requirement has not been satisfied. See also the Guidelines for Examination of Patent Applications under the 35 USC 112, first paragraph, "Written Description" Requirement, 66 Fed.Reg. 1099 (January 5, 2001).

(11) Response to Argument

A. Claim Rejections - 35 USC § 101 (Utility)

The appeal brief filed February 22, 2005 traverses this rejection. Appellant's arguments have been fully considered but are not persuasive for the reasons that follow.

At pages 4-5 the brief traverses that the lack of utility analysis misstates the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" and applies case law in support for the doctrine of "practical utility" and the requirement for "identifiable benefit". These arguments are not specifically drawn to the rejection set forth previously or above, and are an allegation. They are found non-persuasive and

are reasonably an introductory summary set forth by the brief. As a preliminary matter, the rejections in this application are made in order to comply with office policy regarding the utility guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.). So to the extent that any argument conflicts with the guidelines, it will necessarily be non-persuasive.

Appellants assert at page 3 and pages 5-6, that they have met the conditions of providing the public with an invention having substantial utility wherein specific benefit exists in currently available form. Appellants state that, in particular, the claimed nucleic acids can be used to identify a polymorphism in a population of plants. However, this is not considered to be a specific and substantial utility. The utility is not specific because it is a property of all plant nucleic acids that they could be used to search for and try to identify a polymorphism. Further, the asserted utility is not substantial because it is a utility that is performed only to accomplish additional research. All discussions regarding polymorphisms in the specification are generic in nature. The specification does not teach any particular polymorphisms in SEQ ID NO: 7212. The specification does not disclose an association between any particular polymorphisms and any phenotypic trait. Polymorphisms are naturally occurring variations within sequences, which themselves may not have any meaningful use. To determine whether a nucleic acid contains a polymorphism would first require comparing the sequence of SEQ ID NO: 7212 to other newly isolated nucleic acids. Then, upon identifying a nucleic acid variation, one would need to determine whether such a variation had any meaningful use – e.g., whether the variation was associated with a particular trait or characteristic

of a particular strain of plant. Therefore, the nucleic acids of SEQ ID NO: 7212 may only be used to search for polymorphisms and if such polymorphisms are identified then the functional/biological activities of the polymorphisms could potentially be elucidated. Such research projects do not constitute a "real-world" use in currently available form.

As set forth in the MPEP (2107):

> On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":
> (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved;
> (B) A method of treating an unspecified disease or condition;
> (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility;
> (D) A method of making a material that itself has no specific, substantial, and credible utility; and
> (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.

Each of these situations closely matches Appellant's disclosed uses. These uses do not define substantial utilities.

Further, MPEP 2107 states that:

> An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring.

However, in the present situation, the specification does not disclose a correlation between such polymorphisms and any conditions or traits.

Appellants assert that the use of the claimed nucleic acids to detect a polymorphism is analogous to the utilities associated with a microscope, i.e., the claimed nucleic acids may be used to locate and measure nucleic acid molecules in a

sample, cell or organism. However, the use of a nucleic acid to detect a polymorphism is not considered to be analogous to the use of a microscope. The microscope can be used to immediately provide information. For instance, the microscope can be used to identify or distinguish between gram-positive and gram-negative bacteria. This use is well known and its benefits are immediately recognizable. The use of a nucleic acid to detect a polymorphism does not provide information of immediate benefit. If a researcher determines that a polymorphism is present, the researcher would not know what to do with this information since the specification has not disclosed a specific association between any particular polymorphisms and any particular traits. This situation is significantly distinct from a situation in which a nucleic acid is to be used to detect a previously disclosed polymorphism known to be associated with a specific trait. In such a situation, the nucleic acid would have a specific and substantial utility because the information obtained by detecting the polymorphism is specific and of immediate benefit. In contrast, the present invention requires the researcher to first identify a new polymorphism and then determine whether this polymorphism is associated with any particular trait or condition. The information gained by detecting an unknown and uncharacterized polymorphism is not specific and not of immediate benefit.

Appellants assert that the use of the claimed nucleic acid molecules to detect the presence or absence of a polymorphism is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas. However, the gas chromatograph example set forth by Appellant is not analogous to the present disclosure. A gas chromatograph is a piece of equipment designed and built for a

particular use. Such equipment is fully tested, evaluated and calibrated to ensure accurate results. Those skilled in the art know how to use the gas chromatograph to analyze both known and unknown samples. When a sample is unknown, the results may be compared to a standard or reference. However, Appellants have not tested, evaluated or calibrated the claimed nucleic acids for any particular use. Screening for the presence or absence of chlorine in a sample is not equivalent to screening for the presence or absence of an unknown polymorphism. Given that the composition and features of chlorine are well known in the art, the detection of chlorine in a sample has a known meaning to those in the art based upon prior research. In the example discussed in the brief, absent an association between the presence of chlorine and the destruction of a catalyst, the presence or absence of chlorine in a sample would not provide any useful information to the refinery manager. Likewise, the presence or absence of any of the claimed nucleic acids in a sample (or a polymorphism) has no meaning absent an association between the nucleic acid or polymorphism and some other property. Further experimentation is required to determine what that meaning or association might be.

Appellants assert that the specification teaches that the nucleic acids may also be used as markers and probes; to identify and obtain nucleic acid homologues, in microarrays as gene-specific targets; for transformation of plants; to determine the level or expression of a protein or mRNA; to overexpress or suppress a desired protein. However, these utilities are all generic and are characteristic of all nucleic acids. Such uses do not constitute a specific utility. As with the use of a nucleic acid to detect

polymorphisms, a substantial utility for the nucleic acid can only be elucidated once the function of the nucleic acid or the product encoded by the nucleic acid is determined. The present specification does not teach a specific functional or biological activity associated with the nucleic acid of SEQ ID NO: 7212 or a protein encoded by SEQ ID NO: 7212 or an association between the claimed nucleic acids and any particular condition in plants. In the absence of such information, the skilled artisan would not know how to interpret the results of methods which determine the expression of a mRNA or protein and would not know how to use a plant that was transformed with the claimed nucleic acids. Additionally, the use of the claimed nucleic acids as a probe to detect itself does not constitute a specific utility because the result of such a use would be meaningless without additional information regarding the significance of the nucleic acid. The use of the claimed nucleic acids to detect homologues in other plants and organisms such as alfalfa and barley, as argued at page 8 of the brief, is also not a substantial and specific utility. Since the functional activity of the presently claimed nucleic acids is unknown, and the functional activity of any putative homologues is unknown, the detection of such homologues does not provide an immediate benefit and serves only as a starting point for further research. In addition, the use of a nucleic acid in a microarray does not confer a patentable utility since all nucleic acids may be used in microarrays. Each of these asserted utilities are generic, rather than specific. Use of the claimed nucleic acids in the above manners would not be meaningful in the absence of information regarding the specific biological activity or significance of these nucleic acids.

Appellants assert that the claimed nucleic acids may be used to initiate a chromosome walk to identify, e.g., a promoter in the corresponding gene. However, the specification fails to demonstrate that the claimed nucleic acids could in fact be used to obtain any meaningful results from such a search. The specification does not define the structural or functional properties of any promoters associated with SEQ ID NO: 7212. Even if such a promoter exists, there is no specific guidance provided in the specification for identifying the promoter. For instance, the specification does not disclose the location of the promoter, the distance between the promoter and the claimed nucleic acids, or the sequence of the promoter. Initiation of a chromosome walk at the corresponding chromosomal location is considered a non-specific utility because any EST would serve this purpose for isolating an uncharacterized promoter since any chromosomal location would be linked to some promoter. Additionally, since the specification does not describe the corresponding promoter, or any other specific nucleic acid molecule, sufficient to inform one in the art that it has been isolated, there can be no "immediate benefit to the public" in using the claimed nucleic acid molecules in this manner. Appellants assert that the claimed nucleic acid molecules are particularly useful to identify markers and isolate promoters functional in anthers in *Triticum aestivum*, however any nucleic acid similarly isolated as the claimed nucleic acid might be used as such. The specification teaches no function or activity for the protein that SEQ ID NO: 7212 might encode, nor teaches which "important genes" associated with plant growth, quality, and yield would be isolated by the claimed SEQ ID NO: 7212, or what "important developmental, metabolic, and catabolic pathways" SEQ

ID NO:7212 may be a link to. Plant nucleic acids, in general, could be used to "isolate agronomically important genes associated with plant growth, quality, and yield" and could serve as "links in important developmental, metabolic and catabolic pathways." However, the specification provides no specific, or substantial utility that takes advantage of the particular combination of nucleotides in the presently claimed nucleic acid molecule.

At page 9 of the brief, Appellants draw an analogy between golf clubs and nucleic acids. It is stated that "the golf club is generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs." Appellants cite *Carl Zeiss Stiftung v. Renishaw PLC* in support of their arguments. However, the cited decision was made with respect to a mechanical device and not with respect to a molecular compound to be used as a laboratory reagent or a research tool. The facts of the cited case do not correspond to those of the instant application since the utilities associated with a golf club do not compare to the utilities associated with a nucleic acid. While one knows how to use a golf club in a specific manner, one does not know how to use the claimed nucleic acids in a specific manner. The specification does not teach the skilled artisan how to use the claimed nucleic acids for a specific purpose (such as to "hit the ball in a manner that is distinct from other clubs"). Rather, the specification invites the skilled artisan to perform experimentation in order to determine how to use the claimed nucleic acids for a specific purpose.

At page 11, the brief traverses the rejection by arguing that there is no question that the public has recognized the benefits provided by the claimed subject matter. It is

asserted that a multi-million dollar industry has been established with ESTs. However, the evidence provided by Appellants shows that a multimillion dollar industry has arisen surrounding buying and selling EST databases and clones. Appellants have not established the market value of the presently claimed ESTs. Further, it is noted that simply because a product, such as an EST sequence database or a clone library, is bought and sold does not mean that the product has patentable utility.

With regard to Appellant's arguments concerning credibility, the credibility of the asserted uses has not been challenged. It is acknowledged that detection of a polymorphism, for example, constitutes a credible utility. Appellant is reminded that in order to meet the requirements of 35 U.S.C. 101, the specification must disclose at least one utility that is specific and substantial, as well as credible (absent a showing of a well established utility, which would presume that the utility was credible). In the instant situation, the claims remain rejected because the specification does not disclose at least one use that is specific and substantial and no convincing evidence has been provided to show that the disclosed EST, for which only a nucleotide sequence and source have been provided, has a well established utility. Accordingly, the lack of utility remains because there is no well established utility or a specific and substantial utility for the claimed invention.

As set forth above, the rejection is based on the finding that Appellants have not disclosed a substantial and specific or well-established utility for the claimed invention. The facts supporting this conclusion are clearly set forth throughout the rejection. The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148

USPQ 689 (1966) wherein the court held that 35 U.S.C. 101 requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that :

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[I]t is not a reward for the search, but compensation for its successful conclusion."

In the present situation, Appellants have not arrived at a "successful conclusion" as to the actual functional role or significance of the claimed nucleic acids. Without such information, the claimed nucleic acids can only be used as a starting point for conducting further experiments to arrive at a "successful conclusion."

B. Claim Rejections - 35 USC § 112, first paragraph (Enablement)

The brief at page 13 states that this rejection is erroneous and has been overcome by the arguments stated above regarding utility. However, for the reasons set forth above, it is maintained that the uses asserted for the claimed invention are an object of study and are not specific, nor substantial. The specification cannot enable or teach one how to use the invention within 35 U.S.C. 112, first paragraph, if there is no patentable utility within 35 U.S.C. 101. Because there is no utility for the claimed invention for the reasons set forth above, it is maintained that the specification has not enabled the claimed invention.

C. Claim Rejections - 35 USC § 112, first paragraph (Written Description)

The brief traverses the written description rejection. It is argued that the specification demonstrates that Appellant was in possession of the claimed genus of nucleic acid molecules. It is further asserted that the fact that the claims are joined with additional sequences, or complements of the recited sequence or nucleic aid molecules that share a claimed identity with the recited sequence does not mean that Appellant was any less in possession of the claimed nucleic acid molecules. This argument was thoroughly reviewed but was not found persuasive. The rejection is based on the fact that the claims include full length genomic sequences comprising the recited SEQ ID NO: 7212. With regard to claims 8-12, the claims further encompass sequences having 90% to less than 100% identity with SEQ ID NO: 7212 and sequences comprising these variant sequences. Thereby, the claims encompass mutants, allelic variants, splice variants and homologues of SEQ ID NO: 7212 which are not adequately described in the present specification.

Appellants state that the application describes more than just the nucleotide sequence of SEQ ID NO: 7212. It is asserted that the specification describes vectors comprising the claimed nucleic acid molecules, the addition of other nucleotides or detectable labels, fusion peptides, as well as sequences having particular sequence identity to claimed nucleic acid molecules. Appellants cite Enzo Biochem (Fed. Cir. 2002) as stating that the written inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, mixtures of those sequences are also described to one of skill in the art."

These arguments have been fully considered but are not persuasive. The genus of nucleic acids encompassed by the claims is extremely broad and is not limited to vectors comprising the nucleic acids or to nucleic acids comprising a label. The claims further encompass mutants, allelic variants, splice variants and homologues of SEQ ID NO: 7212. A general statement in the specification of a desire to obtain gene sequences, homologues from other species, mutated species, SNPs, polymorphic sequences, promoter sequences and exogenous sequences is not equivalent to providing a clear and complete description of specific sequences which fall within the claimed genus of nucleic acids. As discussed in the rejection, the court in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), held that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". While Appellants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. In the present situation, Appellants have provided only a disclosure of a wish to obtain homologues, mutant, allelic, and splice variants of SEQ ID NO: 7212. The specification does not disclose any specific mutant, allelic, or splice variants or homologues of SEQ ID NO: 7212. Further, the functional activity of such variants is not disclosed. Accordingly, the specification has not disclosed a representative number of nucleic acid molecules within the claimed genus.

Appellants assert that they have disclosed the common structural features of the claimed nucleic acids, i.e., SEQ ID NO: 7212. However, the claims are not limited to nucleic acids which share this common structural feature. Rather, the claims encompass nucleic acids having 90-99.9% identity with SEQ ID NO: 7212. Thereby, the claimed genus of nucleic acids do not share the same common structural feature of containing the sequence of SEQ ID NO: 7212. Appellants have not disclosed what specific sequence information must be shared by the claimed genus of nucleic acid molecules in order to ascertain which nucleic acids share a common structural feature. The genus of molecules having 95-99.9% identity with SEQ ID NO: 7212 includes individual species of nucleic acids which may vary from SEQ ID NO: 7212 at any given nucleotide position within SEQ ID NO: 7212. When the individual species within the genus are compared to one another, together this genus comprises nucleic acids which vary at each and every nucleotide position within SEQ ID NO: 7212. Accordingly, the genus of nucleic acids are not considered to share a common structural feature – i.e., there is no specific structural property that is common to all members of the claimed genus if each of the individual nucleotides may be varied. Further, the claims do not recite a functional requirement for any of the claimed nucleic acids and thereby encompass nucleic acids having distinct functional properties.

At page 17, Appellants state that "closely related nucleic acid molecules falling within the scope of the invention are readily identifiable – they either contain the nucleic acid sequence of SEQ ID NO: 7212 or share a claimed identity with SEQ ID NO: 7212, or they do not. The fact that the nucleic acid molecules may comprise additional

sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. Thus, contrary to the Examiner's analysis, claims 1, 8-12 are supported by an adequate written description." These arguments have been fully considered but are not found persuasive. It is noted that the criteria for meeting the Written Description requirement is not limited to providing a means for distinguishing between molecules which fall within the claimed genus and molecules which fall outside the claimed genus. Rather, the Written Description requirement is met by providing a showing that Appellants were, at the time the application was filed, in possession of the claimed invention. Providing a statement that the invention covers nucleic acid having 90-99.9% identity with SEQ ID NO: 7212 is not equivalent to disclosing specific nucleic acids which fall within the claimed genus of nucleic acids. The specification does not disclose a single molecule within the genus of nucleic acids having 90-99.9% identity with SEQ ID NO: 7212. The specification does not describe the location or identity of nucleotides which may be varied within SEQ ID NO: 7212, and does not describe the functional activity or other biological role associated with such variants. The specification also does not disclose any specific variants of SEQ ID NO: 7212 which have a functional activity or biological role distinct from that of SEQ ID NO: 7212. Modification of a nucleic acid sequence by 1 to 10% can significantly alter the functional activity of the nucleic acid and the protein encoded thereby. The genus of nucleic acids claimed is large and variable, and potentially includes nucleic acids encoding for proteins having diverse biological functions. The specification discloses only one member of this genus, i.e., SEQ ID NO:

7212. This is not sufficient to place one of skill in the art in possession of a representative number of molecules having the varied attributes and features of species within the claimed genus. Accordingly, it is maintained that the written description requirements have not been adequately met for the broadly claimed genus of homologues, splice, mutant and polymorphic variants of SEQ ID NO:7212.

Appellants further argue that Claims 1, 12 are separately patentable, however, each of these claims are drawn to sequences minimally comprising SEQ ID NO: 7212. As noted in the rejection above, the claims recite open transitional language ("having"; "comprising"), and therefore include, e.g., molecules that are 90-100% identical with SEQ ID NO: 7212 and which further include undefined flanking sequences. the claims recite open transitional language ("having"; "comprising"), and therefore include, e.g., molecules that are 90-100% identical with SEQ ID NO: 7212 and which further include undefined flanking sequences. For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Art Unit 1634

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